NOV 1 3 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K013102 **"**

Introduction	According to the requirements of 21 CFR 862.1415, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.
6-1 Submitter Name, Address, Contact	Wiener Laboratorios S.A.I.C. Riobamba 2944 2000 – Rosario – Argentina Contact person: Viviana Cétola Date Prepared: June 20, 2001

6-2 Device Name

Proprietary name: WIENER LAB FER-COLOR TRANSFERRINA
Common name: Photometric method for Total – Iron Binding Capacity determination.
Classification name: Ferrozine (colorimetric) Iron Binding Capacity
Device Class I
Product Code: JMO

6-3 Predicate Device

We claim substantial equivalence to the currently marketed RANDOX TOTAL-IRON BINDING CAPACITY / IRON test system.

6-4 Device Description

End point method.

Transferrin or specific iron carrier protein is assayed through its physiologic activity of binding Fe (III) (TIBC) at a pH higher than 7.2 in which transferrin is saturated in the presence of excess Fe (III). The remaining unbound Fe (III) is totally removed by coprecipitation with magnesium carbonate. After centrifugation, iron in the supernatant is determined as follows: iron bound to transferrin is released and colorimetrically measured according to Fer-Color procedure.

Such measurement proceeds as follows: iron is released from its specific carrier protein (transferrin) in a pH 4.5 acetate buffer, and in presence of a reducing agent (ascorbic acid). Then it reacts with color reagent, pyridyl bis-phenyl triazine sulfonate (ferrozine) producing a colored complex measured at 570 nm.

6-5 Intended Use

Wiener lab FER-COLOR TRANSFERRINA is used for the quantitative determination of Total Iron binding capacity in human serum and plasma. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

6-6 Equivalencies and Differences

WIENER LAB. FER-COLOR TRANSFERRINA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed RANDOX IRON test system.

The following table illustrates the similarities and differences between the WIENER LAB FER-COLOR TRANSFERRINA/ FER-COLOR AA test system and the currently marketed RANDOX TOTAL-IRON BINDING CAPACITY/IRON test system.

	RANDOX Auxiliary Reagents for TIBC	**WIENER LAB. Auxiliary Reagents for TIBC**
Intended use	Quantitative determination of Total - Iron Binding Capacity (TIBC) in human serum.	
Test Principle	An excess of iron is added to the sample to saturate the transferrin. The unbound iron is precipitated with magnesium carbonate. After centrifugation the iron in the supernatant is determined with ferrozine.	
Reagents for Iron Binding capacity	R1 Iron Solution R2 Magnesium Carbonate	
Expected values	46.0 –69.5 µmol/l (259 – 388 µg/dl)	250 – 400 µg/dl

6-7 Conclusion

Based on the data above mentioned, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Dr. Viviana Cetola
QC/QA Manager
Wiener Laboratorios S. A. I.C.
Riobamba 2944,
Rosario, Santa Fe
Argentina

Re: k013102
Trade/Device Name: Fer-Color Transferrina
Regulation Number: 21 CFR 862.1415
Regulation Name: Iron-binding capacity test system
Regulatory Class: Class I, reserved
Product Code: JMO
Dated: July 26, 2001
Received: September 17, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013102

NOV 1 3 2001

510(k) Number (if known): K013102

Device Name: Wiener lab.
Fer-Color Transferrina

Indications For Use:

The "Wiener lab. Fer-Color Transferrina" iron-binding capacity test system is a quantitative in vitro diagnostics device intended to measure iron-binding capacity in serum or plasma. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory D
510(k) Number K013102

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

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